K022581

510K Summary of Safety and Effectiveness

1. **Submitted By:**

OCT 09 2002

John Schalago
Manager, Regulatory Affairs

Becton Dickinson Consumer Healthcare
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2. **Device Name:**

Trade Name: BD Logic™ Blood Glucose Monitor

Common Names: Glucose oxidase, glucose test system

Classification Name: Glucose oxidase, glucose test system

3. **Predicate Device:**

Glucometer DEX Test Sensor

Manufactured by: Bayer Diagnostics

4. **Device Description:**

The BD Logic™ Blood Glucose Monitor is intended for use in the quantitative measurement of glucose in capillary blood collected from fingertips.

The BD Logic™ Blood Glucose Monitor is designed to be simple and easy to use. It provides accurate blood glucose test results in 5 seconds using a small (0.3 µL) sample volume. The system also offers the convenience of containing all of the daily needs for diabetes care in one place as the System includes the blood glucose meter and conveniently holds the test strip vial, lancing device, spare lancets, insulin pen and additional insulin pen needles.

510K Summary of Safety and Effectiveness (*Continued*)

5. **Intended Use:**

The BD Logic™ Blood Glucose Monitor is intended for use in the quantitative measurement of glucose in whole blood. It is intended for use by people with diabetes mellitus in the home as an aid to monitor the effectiveness of diabetes control. It is not intended for use in the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

The BD Logic™ Blood Glucose Monitor is specifically indicated for the quantitative measurement of glucose in whole blood samples obtained from the fingertip.

6. **Technological Characteristics:**

The BD Logic™ Blood Glucose Monitor is based on biosensor technology. When blood is applied to the Blood Glucose Test Strip, reagents on the test strip react with the blood and a current is generated. The BD Logic™ Blood Glucose Monitor employs amperometric technology to measure the glucose concentrations in the blood sample by measuring the amount of current that is generated and flows through the electrodes on the test strip.

7. **Performance Summary:**

Laboratory and clinical studies demonstrate that the BD Logic™ Blood Glucose Monitor performed in an equivalent manner to the predicate and is suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. John A. Schalago MS, RAC
Regulatory Affairs Manager
Becton, Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417

OCT 9 - 2002

Re: k022581
Trade/Device Name: BD Logic™ Blood Glucose Monitor
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW; JJX, CGA
Dated: August 2, 2002
Received: August 5, 2002

Dear Ms. Schalago:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022581

Device Name: BD Logic™ Blood Glucose Monitor

Indications For Use:

The BD Logic™ Blood Glucose Monitor is intended to be used for the quantitative measurement of glucose in whole blood. It is intended for use by people with diabetes mellitus in the home as an aid to monitor the effectiveness of diabetes control. It is not intended for use in the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

The BD Logic™ Blood Glucose Monitor is specifically indicated for the quantitative measurement of glucose in whole blood samples obtained from the fingertip.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022581

Over-the-counter ✓